REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim Amendments

Claim 1 has been amended to recite "under the condition that a combination of a drug administration period of 1 day to about 14 days and a drug holiday period of 1 day to about 14 days is repeated". Claim 5 has been amended to delete "to 16 days".

Support for these amendments is found in paragraph [0041] of the present specification.

Telephonic Interview

Applicants wish to kindly thank the Examiner for participating in a telephonic interview with Applicants' representative on January 6, 2011.

During the interview, Applicants' representative proposed amending claim 1 to recite, "...under the condition that a combination of a drug administration period of 1 day to about 14 days and a drug holiday period of 1 day to about 14 days is repeated during the period for treating the disease or suppressing the progression of the disease." Applicants' representative discussed the unexpected results presented in the Declaration filed February 3, 2010, as well as the Examples set forth in the specification, which demonstrate superior results achieved by Applicants' method. Applicants' representative noted that this data provided results for two dosing regimens within the proposed range.

The Examiner kindly indicated that such an amendment would address his concern, and overcome the obviousness rejection.

Applicants appreciate the Examiner's helpful comments, and have amended the claims in accordance with the discussion.

Rejection Under 35 U.S.C. § 103(a)

The patentability of the present invention over the disclosure of the reference relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Claims 1 and 3-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ikeda (WO 02/34264). This rejection is respectfully traversed.

The Position of the Examiner

The Examiner takes the position that Ikeda et al. recite a method of treating amyotrophic lateral sclerosis (ALS) or symptoms caused by ALS and/or suppressing the progression thereof, comprising administering edaravone to a patient. The Examiner acknowledges that Ikeda et al. fail to teach the specific dose regimens which includes holiday periods. On page 9 of the Office Action, the Examiner indicates that this rejection was previously withdrawn based on data presented by Applicants on January 21, 2010 and the Declaration dated February 3, 2010. The Examiner now indicates that the data presented is not commensurate in scope with the claims. Specifically, the Examiner states that although Applicants demonstrated unexpected results for the particular dosing regimen disclosed in the Declaration, this set of data may not be extrapolated to other dose regimens, for example where the administration of edaravone is given for 100 consecutive days followed by one or two holiday periods.

The Position of Applicants

As discussed previously, Applicants contacted the Examiner to discuss proposed amendments to the claims which would address the Examiner's concern. The claims have been amended to include a dosing regimen which the Examiner indicated as acceptable. Detailed comments in this regard are provided below.

Claim 1 has been amended to recite that the method is under a condition that a combination of a drug administration period of 1 day to about 14 days and a drug holiday period of 1 day to about 14 days is repeated during the period for treating the disease or suppressing the progression thereof.

As acknowledged by the Examiner, Applicants have previously provided data demonstrating unexpected results for a drug administration of two days with a holiday period of two days, then two days of drug administration followed by two holiday days. Specifically, the group with the drug holiday period showed a more excellent effect (suppression of reduction of food consumption) than the group with daily administration. Please see the Declaration submitted February 3, 2010.

Additionally, the Examples provided in the specification further demonstrate the unexpected and advantageous results of Applicants' method. Examples 1 and 2 in the specification apply the following dosing regimen: drug administration for 14 days (1st administration period), holiday for 14 days, drug administration for 10 days (with no administration on Saturday, Sunday or holiday) (2nd administration period), and then treatments similar to the 2nd administration period repeated 4 times. Example 1 showed suppression of ALSFRS-R score, which is a rating for ALS. Example 2 showed suppression of decrease of % FVC (percent predicted forced vital capacity, which is generally used as an index in a method for objectively evaluating respirator function in ALS patients), and increase of $PaCO_2$ (partial pressure of arterial carbon dioxide).

Thus, in view of the claim amendments, as well as the data discussed above, Applicants respectfully assert that the present claims are patentable over the teachings of the cited reference. Withdrawal of the rejection is respectfully requested.

Conclusion

Therefore, in view of the foregoing amendments and remarks, it is submitted that the ground of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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